

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of: Curtis Wright, IV Confirmation No.: To be assigned

Serial No.: Continuation of U.S. Application Art Unit: To be assigned  
No. 09/714,604

Filed: On even date herewith Examiner: To be assigned

For: TITRATABLE DOSAGE Attorney Docket No.: 6750-237  
TRANSDERMAL DELIVERY  
SYSTEM

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

1. Enclosures accompanying this Information Disclosure Statement are:
  - 1a. ☒ A list of all patents, publications, applications, or other information submitted for consideration by the office.
  - 1b. A legible copy of :
    - ☐ Each U.S. patent application publication and U.S. and foreign patent;
    - ☐ Each publication or that portion which caused it to be listed on the PTO-1449;
    - ☐ For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion;
    - ☐ all other information or portion which caused it to be listed on the PTO-1449.
  - 1c. ☐ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report.
  - 1d. ☐ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications.
2. ☒ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):
  - ☐ Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);
  - ☐ Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;

- ☒ Before the mailing of the first Office action on the merits;
- ☐ Before the mailing of a first Office action after the filing of a request for continued examination under §1.114.

3. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R. §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.

*(Check either Item 3a or 3b)*

- 3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.
- 3b. ☐ The \$180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:
- ☐ enclosed
- ☐ to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.

*(Item 3b to be checked if any reference known for more than 3 months)*

4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.

The \$180.00 fee set forth in 37 C.F.R. §1.17(p) is:

- ☐ enclosed.
- ☐ to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.

The Certification Statement in Item 5 below is applicable.

5. ☐ Certification Statement (applicable if Item 3a or Item 4 is checked)

*(Check either Item 5a or 5b)*

- 5a. ☐ In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- 5b. ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not **received** by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.
- 5c. ☐ Pursuant to 37 C.F.R. §1.704(d), each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not **received** by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.

6. ☒ This application is a continuation application under 37 C.F.R. §1.60 or §1.53(b) or (d).

(Check appropriate Items 6a, 6b and/or 6c)

- 6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently filed herewith.
- 6b. ☒ Copies of publications listed on Form PTO-1449 from prior application Serial No. 09/714,604, filed on November 16, 2000, of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).
- 6c. ☐ Copies of the publications listed on Form PTO-1449 were not previously cited in prior application Serial No. , filed on , and are provided herewith.
7. ☐ This is a Supplemental Information Disclosure Statement. (Check Item 7a)
- 7a. ☐ This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on . A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on .
8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:

( Check Item 8a, 8b, or 8c)

- 8a. ☐ satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.
- 8b. ☐ set forth in the application.
- 8c. ☐ enclosed as an attachment hereto.
9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Pennie & Edmonds LLP Deposit Account No. 16-1150.
10. ☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability nor a representation that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

Respectfully submitted,

*Gidon D. Stern by:*

Date: October 20, 2003

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Enclosures

## LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO.

6750-052

APPLICATION NO.

09/714,604

APPLICANT

Wright and Curtis

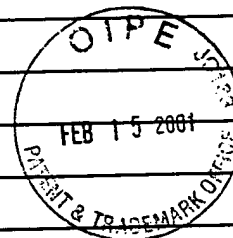
FILING DATE

November 16, 2000

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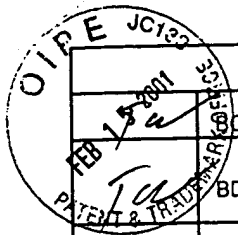
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## OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

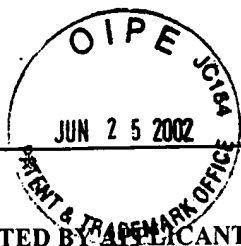
BC	Edinboro et al., 1997, "Fatal fentanyl intoxication following excessive transdermal application", J Forensic Sci. Jul;42(4):741-3
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BM	Popli S et al., 1983, "Transdermal clonidine for hypertensive patients", Clin Ther. 5(6):624-8.
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BO	Southam M.A., 1995, "Transdermal Fentanyl Therapy: System Design, Pharmacokinetics and Efficacy", Anti-cancer Drugs 6 Suppl. 3: 29-34
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BQ	Wang et al., 2000, "Pharmacokinetics of transdermal testosterone gel in hypogonadal men: application of gel at one site versus four sites: a General Clinical Research Center Study", J Clin Endocrinol Metab. 85(3):964-9.
BR	Woolf et al., 1996, "Self-poisoning among Adults Using Multiple Transdermal Nicotine Patches", J. Toxicol. Clin. Toxicol. 34(6):691-8

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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## LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO.

6750-052-999

APPLICATION NO.

09/714,604

APPLICANT

Curtis Wright IV

FILING DATE

November 16, 2000

GROUP

1615

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
BS <i>TW</i>	6,143,320	11/7/00	Becher et al.			

## FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO

## OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)


EXAMINER

*Todd G. Ward*

DATE CONSIDERED

10-20-02

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ATTORNEY DOCKET NO.

6750-052

APPLICATION NO.

09/714,604

APPLICANT

Curtis Wright, IV

FILING DATE

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CLASS

1615

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILED DATE IF APPROPRIATE
TW	BT	5,066,494	11/19/91	Becher			

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							YES	NO
TW	BU	EP 0 559 411 A1	09/08/92	EPO				
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	BW	EP 0 298 297 A1	11/19/91	EPO (with English Abstract)				

## OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)


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7-14-03

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APPLICANT

Curtis Wright, IV

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## U.S. PATENT DOCUMENTS

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## FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
					YES NO

## OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

<i>TW</i>	BX	Carroll, "Estrogen patch may be safer for heart than pill," Reuters Health, April 2003

EXAMINER

*[Signature]*

DATE CONSIDERED

7-14-03

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<b>Notice of References Cited</b>	Application/Control No. 09/714,604		Applicant(s)/Patent Under Reexamination WRIGHT, CURTIS	
	Examiner Todd D Ware		Art Unit 1615	Page 1 of 1

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*	B	US-6,221,384	04-2001	Pagedas, Anthony C.	424/448
	C	US-6,054,120	04-2000	Burgoyne et al	424/59
*	D	US-5,686,112	11-1997	Liedtke, Rainer K.	424/444
	E	US-5,616,337	04-1997	Kasianovitz et al	424/414
*	F	US-5,438,067		Jalonen et al.	424/447
*	G	US-4,915,950	04-1990	Miranda et al.	424/447
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

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	N					
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	S					
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**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
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